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EXAMINER

YOUNG, MICAH PAUL

ART UNIT PAPER NUMBER

1618

MAIL DATE DELIVERY MODE

11/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/623,481

Applicant(s)

LIM ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 29-39 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28, 40, 41, 43-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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DETAILED ACTION**Acknowledgment of Papers Received:** Amendment/Response dated 7/24/07.***Election/Restrictions***

1. Applicant's election with traverse of the species election in the reply filed on 9/28/06 is acknowledged. The traversal is on the ground(s) that the claims are more drawn to the release of the active agents and their formulation not the specific functionality of the individual drugs. This is not found persuasive because the disparity in subject matter in the claimed drugs represent a burden on the examiner since each group of drugs is classified separately and would represent a separate and independent search.

The requirement is still deemed proper and is therefore made FINAL.

Applicant has elected species corresponding to claims 1-28,40,41 and 43-46.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-28,40,41 and 43-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,682,759. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to a method of making a pharmaceutical tablet comprising dispersing a first drug solution onto a substrate making a unitary dosage form, depositing on the unitary dosage a polymeric layer, and depositing over that layer a second drug solution, next evaporating the solvent. The '759 patent claims are drawn an identical process save for a ratio of first to second drug. There is essentially no difference between the instant claims and the '759 patent. The '759 claims recite a ratio of the first drug to the second drug however this would be well within the skill of an ordinary artisan and would have been an obvious modification resulting from routine experimentation. The instant claims recite the same method applying the same components to a core using the same drugs of the same particle size. The '759 patent claims a method of manufacturing a pharmaceutical tablet comprising dispersing a second drug in to a solid matrix, coating the matrix with a layer not comprising any drug, and depositing over the layer a first drug, followed by evaporating the water form the tablet. The instant claims recite a nearly identical method of manufacture differing only in the ratio of first to second drugs and a recitation of drug particle size. The '759 patent would act as obviating art over the instant claims if issued.

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Johnson et al (USPN 6,171,618 hereafter '618). The claims are drawn to a method of making a pharmaceutical dosage form comprising depositing a first drug onto

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a matrix, depositing successive layers of controlled releasing polymers and a second drug onto the matrix, followed by driving off any solvents used.

8. The '618 patent is drawn to a method of making a combination dosage form comprising two separate drugs having different release rates (abstract). The first drug (the controlled release agent) is released so that at least 75% of the drug is released over a period of 4-36 hours (col. 3, lin. 10-15). The first drug is formed into a core with a solid matrix material such as microcrystalline cellulose and hydroxypropyl cellulose (col. 17, lin. 50-55). The core is then coated with a solution of a polymer matrix not comprising a drug and can fully encompass the core or cover sections having pores (col. 18, lin. 5-10; col. 10, lin. 8-68). The pores measure less than 50 microns, meaning the drugs must measure far below 50 microns (col. 10, lin. 55-60). The polymer matrix comprises polyvinyl alcohol (col. 9, lin. 25). The resultant coated core is further coated with a drug formulation (col. 18, lin. 30-40). The tablets are dried leaving a solid two drug controlled release agent with the top drug formulation releases immediately while the inner coated drug releases slower (examples). Solvents include water, ethanol and acetone (example). The weight ratio of the polymeric film to the unitary body (core) is approximately 0.16:1 (example 2).

9. The reference differs from the instant claims in disclosures of the ratio of unitary dosage from to the polymeric film, however this limitation is well within the limits of one of ordinary skill in the art to manipulate and arrive at through routine experimentation. The reference is further silent to the specific amount of first drug is release within the first hour. Although 75% of the drug is release over a period of 4-36 hours, there are no explicit disclosures for the first hour. However it is the position of the Examiner that this

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release rate like many properties can be manipulated and derived from routine experimentation. As discussed above the ratio of polymeric film to unitary dosage overlaps the range of the instant claims (0.16:1). It is the position of the Examiner that these specific ratios represent an optimized result determined through routine experimentation and do not impart patentability on the claims.

10. With the things in mind it would have been obvious to one of ordinary skill in the art to follow the suggestions of the art to follow the teachings and suggestions of the art in order to provide a stable combination therapy useful in treating various disorders. One of ordinary skill in the art would have been motivated to follow these teachings with an expected result of a combination therapy useful in treating various disorders.

11. Claims 40,41 and 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Johnson et al (USPN 6,171,618 hereafter '618) in view of Timmins et al (USPN 6,031,004 hereafter '004) and Sauerberg et al (USPN 6,274,608 hereafter '608).

12. As discussed above the '618 patent discloses a combination therapy wherein the separate drugs have distinct release profiles. The reference differs in the specific drugs recited however the inclusion of specific agents in a pharmaceutical dosage form is well within the level of skill in the art as seen in the '004 and '608 patents.

13. The '004 patent discloses a combination therapy comprising metformin salts and sulfonylurea agents (abstract). The sulfonylurea agents include glyburide, glimepiride, gliprider, glipizide and other well-known diabetic treatment agents (col. 4, lin. 24-28). The metformin salts include hydrochloride (col. 4, lin. 59-68). It would have been

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obvious to combine the drugs into the formulation of the '618 patent since both formulation comprise similar cellulose based controlled releasing agents.

14. The '608 patent discloses a combination therapy comprising various ACE inhibitors and sulfonylurea compounds. The ACE inhibitors include benazepril, captopril and ramipril (col. 12, lin. 20-30), while the sulfonylurea agents include metformin (col. 12, lin. 10-17). The formulation further comprises cellulosic materials as controlled releasing agents (col. 13, lin. 50-60). It would have been obvious to combine the drugs of patent into the '618 patent since they both comprise similar control releasing agents.

15. With these aspects in mind it would have been obvious to combine the specific drugs of the '608 and '004 patent into the formulation of the '618 patent in order to impart specific therapeutic properties on the formulation. One of ordinary skill in the art would be motivated to combine the teachings with an expected result of a combination therapy capable of treating various disorders.

Response to Arguments

16. Applicant's arguments filed 7/24/07 have been fully considered but they are not persuasive. Applicant argues that:

- a. The '618 patent does not disclose a polymeric film that is soluble in gastrointestinal fluid
- b. The '618 patent does not disclose a sustained release core coated with a film over the matrix.
- c. The weight ratio of the instant invention distinguishes over the '618 patent.

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17. Regarding argument a. and b., it remains the position of the Examiner that the polymeric film of the '618 patent meets the limitations of the instant claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the immediate dissolution of the polymeric film and release of the active agent and that the core is sustained release matrix) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Specifically regarding the instant claims the polymeric film is recited to be selected from a group of polymers including polyvinyl alcohol. Polyvinyl alcohol is recited in the prior art as being a possible useful polymer in the membrane coating. Although the purpose of the coating is to retard the release of the active agent, portions of the film will and do dissolve in GI fluids over time. Applicant has not provided a time frame or specifics on how the polymeric film dissolves or is solubilized by the GI fluids. Further since the prior art provides the same polymer recited in the claims it must perform all the functions of the instant invention unless proven otherwise.

18. Applicant also argues that the matrix core of the instant claims is designed for sustained release while the coating is designed for immediate dissolution. The core of the instant claims is not claimed as a sustained releasing core, just as the polymeric film is not recited as an immediate releasing layer. The core components of the instant claims are identical to those of the prior art. Specifically a solid matrix comprising microcrystalline cellulose or hydroxypropylcellulose with a coating comprising polyvinyl alcohol (examples). Applicant argues that the '618 patent does not provide a sustained

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release matrix core and a film over the matrix, however this combination is not claimed.

What is claimed however is a solid matrix comprising a cellulose ether and a film covering the core comprising a polyvinyl alcohol. The '618 patent discloses a solid matrix core comprising microcrystalline cellulose and hydroxypropylcellulose, covered with a film coating (example 2). For these reasons the claims remain obviated by the '618 patent.

19. Regarding argument c., applicant argues that the weight ratio is too far outside the range of the instant claims. However claim 11 establishes a large range of 0.5%-20% for the weight percentage of the polymeric film. The '618 patent exemplifies a weight percentage of approximately 16% falling within the wider range. Applicant argues that there is no room for modification or optimization since the purpose of the membrane coating of the '618 patent is to retard release and a thinner coating (seemingly to provide a lower weight ratio of polymer) would not provide this result. Applicant has not taken into consideration the components of the core and membrane coating. The core could include more of a particular component weighing more, while the membrane coating could maintain the same thickness. This would provide a lower weight ratio while maintain the prolonged release required by the membrane coating. All of these modifications would have been within the level of ordinary skill in the art and would have been obvious to an ordinary artisan. For these reasons the claims remain obviated by the '618 patent.

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Conclusion

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

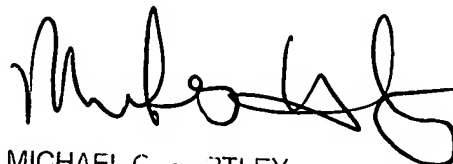
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MP Young

Micah-Paul Young
Examiner
Art Unit 1618


MICHAEL G. CORTLEY
SUPERVISORY PATENT EXAMINER